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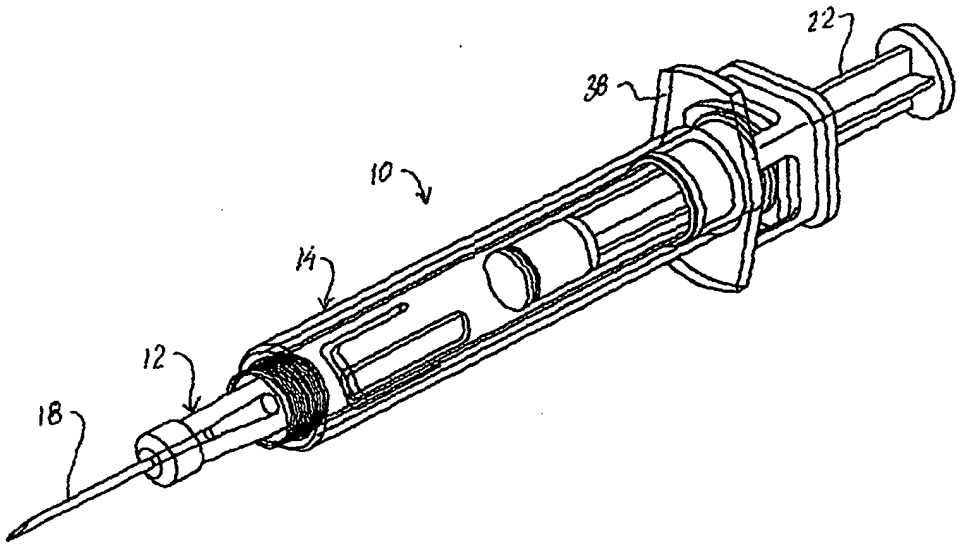
(54) Title: SAFETY SHIELD SYSTEM FOR PREFILLED SYRINGES



(57) Abstract: A medical device (10) is provided which includes a shield system (14) and a syringe (12) which is coupled to the shield system. The shield system includes a syringe holder (26) and a shield (28) which is slidably coupled to the holder. A spring (30) resiliently urges the shield from a retracted position to an extended position. Stop members (48, 52) are provided on the holder and shield for maintaining the shield in the retracted position. The syringe is slidably coupled to the holder, and extends within the shield. Axial movement of the syringe with respect to the holder causes disengagement of the stop members, allowing the spring to move the shield to the extended position. Detends (58, 59) are provided on the holder for maintaining the shield in the extended position.

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SAFETY SHIELD SYSTEM FOR PREFILLED SYRINGES

BACKGROUND OF THE INVENTION

The field of the invention relates to shield systems for protecting against needle sticks, and syringes including such systems.

Brief Description of the Related Art

Syringes are well known medical devices for administering medicaments to patients. Prefilled syringes are generally considered as those which are filled with a selected dosage of medicament by a pharmaceutical manufacturer for distribution to the end user. They are often comprised of a glass or plastic barrel which contains the medicament and a piston slidably mounted within the barrel. One end of the barrel includes a needle or the like affixed thereto or a connector for a needle assembly such as a Luer fitting. The other end of the syringe is open to allow the insertion of a plunger rod. The plunger rod allows the user to apply manual force to the piston, causing the medicament to be delivered through the needle or other piercing element.

The use of a sharp-pointed piercing element entails the risk of accidental needle stick. To avoid such accidents, many prior art hypodermic syringes have included rigid cylindrical safety shields telescoped over the syringe barrel. These shields can be moved between retracted positions where the needles are exposed for use, to extended positions where the needles are surrounded by the shields. U. S. Patent Nos. 4,425,120, 4,573,976, 4,850,994 and 4,923,447 disclose various shield systems for hypodermic syringes. The latter two patents disclose shields which are spring-actuated. It is ordinarily desirable to lock the needle shields in the protected positions, and a number of prior art designs provide for such locking. Some systems, such as those disclosed in U. S. Patent Nos. 5,201,708, 5,242,240 and 5,318,538 are designed to allow the shields to be retracted from their locked, extended positions.

A shield system for protecting the piercing element of a prefilled syringe is disclosed in European Publication No. EP 0 740 942 A1. The disclosed system includes a holder which is coupled to the flange of the syringe barrel, and a shield which is telescopically mounted to the holder. Two hands are required to operate this system

SUMMARY OF THE INVENTION

The invention relates to a safety shield system for a syringe, and such a system as used in combination with an assembly capable of functioning as a syringe. In accordance with the preferred embodiment of the system, the user is able to cause the shielding of a needle by simply applying pressure to the plunger rod of the syringe following injection of the contents of the syringe barrel. The shield may accordingly be deployed automatically through the use of only one hand. As there is no need to place the hand near the needle for any purpose, the risk of needle stick injury is reduced.

In accordance with the objects of the invention, a medical device is provided which includes an automatically operable shield system mounted to a syringe barrel. The system includes a holder which defines an enclosure. The syringe barrel extends at least partially, and preferably almost entirely, within the enclosure. The barrel is slidable within the holder. A shield is mounted to the holder, and positioned about at least a portion of the barrel. The shield is axially movable with respect to the holder between retracted and extended positions. It is intended to cover the needle tip when in the extended position. A spring engages the shield, and urges it towards the extended position. A stop member is positioned on the holder for releasably engaging the shield when the shield is in the retracted position. The force of the spring, by itself, is insufficient to cause disengagement of the shield and stop member. The barrel is operationally coupled to the shield such that sufficient axial movement of the barrel causes axial movement of the shield sufficient to cause disengagement of the shield and stop member. Such movement of the barrel is ordinarily caused by pressure on the plunger rod of the syringe following complete injection of the contents of the barrel. Upon disengagement of the shield and stop member, the spring causes the shield to move to the extended position.

The proximal end of the holder is preferably adapted to engage and retain the flange which may be present at the proximal end of the syringe barrel. The axial movement of the shield is preferably limited by a set of locking detents formed on the holder. Such movement could alternatively be limited by a tether connecting the holder and shield. The shield includes a distal end portion which is engaged by one end of the spring. The opposite end of the spring can bear against any suitable surface, such as the flange on the syringe barrel, if present, or preferably an abutment of an end fitting slidably positioned within the holder.

The shield system according to the invention is comprised of a holder, a shield, a spring and, preferably, an end fitting. The holder is adapted for receiving the barrel of a syringe. The shield is positioned within and connected to the holder, and is movable between retracted and extended positions. A spring engages the distal end portion of the shield and urges it towards the extended position. The holder includes a stop member which is engageable with the shield to maintain it in the retracted position. Sufficient axial movement of the shield causes disengagement of the stop member, allowing the spring to move the shield to the extended position. An end fitting is preferably incorporated in the system to maintain the position of the spring against the shield.

The shield system facilitates the safe use of prefilled syringes, though it can be adapted for other sharp-pointed medical devices, such as syringes filled just before use, as well. When employed with a syringe, the system allows the contents of the syringe to be expressed in a conventional manner. Continued, and preferably increased pressure on the plunger rod following injection causes the syringe barrel to move axially, thereby axially displacing the shield. Such displacement causes release of the stop member, and the spring to move the shield over the needle of the syringe. Protection against needle sticks is accordingly provided.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a top perspective view of a preferred embodiment the medical device according to the invention as assembled;

Figure 2 is an exploded, perspective view thereof;

Fig. 3 is a sectional elevation view thereof;

Fig. 4 is a sectional view thereof following actuation of the shield system of the device;

Fig. 5 is an enlarged sectional view of the proximal portion of the device prior to actuation of the shield system;

Fig. 6 is an enlarged sectional view showing a distal portion of the device prior to actuation of the shield system;

Fig. 7 is an enlarged sectional elevation view of a proximal portion of the device following actuation of the shield system; and

Fig. 8 is an enlarged sectional elevation view of the distal portion of the device following actuation of the shield system.

DETAILED DESCRIPTION OF THE INVENTION

A medical device 10 for injecting a medicament into a patient is shown in Figures 1-8. The device comprises a prefillable syringe 12 and a shield system 14 coupled to the syringe, as shown in Fig. 1.

Syringes are ordinarily comprised of a generally cylindrical portion, known as a barrel, a needle or other piercing or connecting element secured to one end of the barrel, and a piston or stopper slidably positioned within the barrel. The needle may be removably secured to the barrel, but is more likely to be permanently secured to the barrel when the barrel is comprised of glass. Glass barrels are commonly used in prefillable syringes, and ordinarily contain a single dose of medication. Prefilled syringes made from plastic are also known to the art. The shield system 14 disclosed herein is employed in conjunction with a prefillable syringe including a barrel 16, a cannula such as a needle 18 permanently secured to the barrel, a piston 20 slidably positioned with the barrel, and a plunger rod 22 engageable with the piston as shown in Fig. 2. The syringe barrel 16 includes a radially outwardly extending flange 24, which is used to couple the syringe to the shield system.

The shield system 14 according to the invention includes a holder 26, a shield 28 coupled to the holder, and a spring 30. It also preferably includes a holder end

fitting 32 which engages one end of the spring. With the exception of the spring, all of the components of the system are made from a semi-rigid plastic material such as polypropylene. The spring is preferably a metal coil spring.

The holder 26 is preferably comprised of an elongate, generally cylindrical body 34 which defines a generally cylindrical enclosure. The holder has proximal and distal open ends which provide access to the enclosure. A flange 38 extends radially outwardly from the holder body near the proximal open end thereof. The flange and body of the holder are designed for easy handling as an injection is made. Only one hand should be required for injection.

The inner surface of the holder includes a frustoconical portion 40 adjoining the proximal open end, as best shown in Fig. 5. A first abutment surface 42 is formed at the inner end of this surface. A second abutment surface 44 is formed by the holder body in opposing relation to the first abutment surface. As described below, the axial spacing between these surfaces corresponds, though may not be equal to the axial distance which the syringe can move with respect to the holder. The inner diameter of the holder, measured at the abutment surfaces, is smaller than the distance between the edges of the syringe flange 24. Accordingly, once the syringe is inserted far enough into the holder that the flange 24 is between abutment surfaces 42, 44, it is slidably coupled to the holder. The spring 30 urges the syringe flange into engagement with the first abutment surface 42.

A generally annular stop member 48 is provided on the holder in the form of an inwardly extending protrusion, as shown in Fig. 6. Alternatively, a series of discrete protrusions (not shown) may be employed. The stop member is positioned at or near the distal end of the holder, and is preferably integral with the holder. A slot or other equivalent feature (not shown) may be provided in the holder near the stop member to provide flexibility therein.

A first detent 50 is provided at or near the first open end of the holder. The detent 50 may be in the form of an annular shoulder formed in the holder. Alternatively, the detent may be in the form of radially inwardly extending projections

(not shown). The exact structure of the detent is not considered to be critical so long as it is capable of functioning satisfactorily in the manner described hereafter.

A second pair of detents 52 are provided on the holder, and are axially spaced from the first detent as shown in Fig. 6. Each of these detents 52 is formed on an axially extending arm 54 which is integral with the holder body 34 and pivotable with respect thereto. The end surface of each detent facing the distal open end of the holder is substantially perpendicular to the longitudinal axis of the holder. An inclined end surface is provided on the opposite side of each detent, and faces the proximal open end.

The shield 28 is comprised of a substantially cylindrical body 56 as shown in Fig. 8. It is preferably small enough in diameter to be positioned within the holder, and large enough to fit over the barrel 16 of the syringe and the end fitting 32. A stop member 58 in the form of a radially outwardly extending collar is formed on the body 56 of the shield near the distal end thereof. A second radially outwardly extending collar is formed on the body 56 towards the proximal end, and defines a further stop member 59. The second collar is larger in diameter than the first. Openings 60 in the shield provide flexibility for the shield body.

The spring 30 is sized to fit within the shield and over a reduced diameter portion of the end fitting. As shown most clearly in Figs. 6 and 8, a spring retainer in the form of an annular enclosure 46 is defined by the distal end of the shield. One end of the spring is positioned within this enclosure, and bears against the end wall of the shield. The other end of the spring abuts a shoulder portion 33 of the end fitting.

The spring may be used to cause the shield to move axially upon axial movement of the syringe barrel if it is fully compressed when the shield is in the retracted position. Direct engagement of the end fitting 32 and shield, as provided in the preferred embodiment, would be unnecessary in such an arrangement.

The end fitting 32 includes a generally cylindrical body 64 having a distal portion 65 of reduced diameter, as shown in Fig. 8. One end of the spring 30 fits over

the reduced diameter portion, an abuts the shoulder 33. An annular wall 66 is provided at one end of the cylindrical body 64, and is preferably integral therewith. This wall extends radially outwardly with respect to the cylindrical body 64. The wall is adapted to engage the first abutment surface 42, so that it can be snapped behind the frustoconical portion at the proximal open end of the holder. The end fitting maintains the spring 30 in position within the holder, thereby allowing the shield system to be manufactured as an assembly which does not include the syringe. Axial movement of the syringe causes corresponding axial movement of the end fitting, which in turn urges the shield 28 in the distal direction.

The assembly and use of this preferred embodiment of the invention shall now be described. The shield 28 is slidably mounted to the holder by inserting it through the proximal open end thereof. The engagement of the stop members 48, 58 limits such insertion. The spring is inserted through the proximal open end of the holder, and within the shield until one end is positioned within the enclosure 46 and abuts the end wall of the shield. As a final step prior to providing the shield system to the end user, the end fitting 32 is inserted within the holder and into the other end of the spring. The spring is substantially compressed during this step. Once the annular wall 66 snaps over the frustoconical portion 42 of the holder, assembly of the shield system is complete. The shield is resiliently urged towards the distal end of the holder while the end fitting is urged towards the proximal end thereof. Neither element can move due to the engagement of the stop members 48, 58, and the annular wall 66 with the first abutment surface 42, respectively. The force of the spring 30 is insufficient to cause the disengagement of these members. The shield system may be provided to end users or pharmaceutical manufacturers in this form, ready for the insertion of a prefilled syringe.

The shield system 14 receives a syringe of appropriate size through the proximal open end of the holder. The syringe is in sliding engagement with the inner surface of the end fitting. The system as shown is designed for receiving a syringe including a flange. The syringe is inserted into the shield until the flange 24 snaps behind the first abutment surface 42. The end fitting 32 is displaced slightly during this procedure. As the needle of the syringe is ordinarily protected by a cover at this time, it may be safely coupled to the shield system.

The force required to disengage the stop members 48,58 should be greater than the force required to expel the contents of the syringe barrel. The plunger rod is employed to move the piston 20 down the syringe barrel until the contents of the barrel have been completely expelled. (The cover is, of course, removed prior to injection.) The contents of the barrel of a prefillable syringe ordinarily correspond to a single dose of the prescribed medicament.

Following removal of the needle 18 from the patient, the user applies a greater force to the plunger rod than that applied during injection. Such force causes axial displacement of the end fitting, the spring and the shield with respect to the holder. The distance between the annular wall 66 of the end fitting (or the flange 24) and the second abutment surface 44 is sufficient to allow the second stop member 58 to move far enough axially to where its retention by the first stop member 48 is overcome by the force of the spring. In the preferred embodiment, this is accomplished as the stop members slide past each other. The first stop member 48 may also be displaced radially as such sliding occurs if insufficient flexibility of the holder body is provided.

Once the stop members 48, 58 are disengaged, the spring 30 expands rapidly, causing the shield to slide axially with respect to the holder and syringe barrel to the position shown in Fig. 4. The stop member 59 moves past the second detents 52, causing them to deflect radially outwardly and then inwardly to their original positions. It finally engages the first detent 50. Upon such engagement, the needle 18 is entirely and permanently covered by the shield, as shown in Figs. 4 and 8. The shield cannot be retracted sufficiently to expose the needle tip due to the engagement of the stop member 59 with the second detents. It cannot be removed from the holder as the stop member 59 cannot move past the first detent 50.

The above-described procedure is particularly safe as it can be accomplished using only one hand. No second hand is required to push a button or use any other actuating member to release the spring. The risk of accidental actuation of the shield through inadvertent contact with an actuating button is eliminated. Moreover, a one-handed system is simpler for most people to use. It is readily apparent that the shield

system can be adapted for use with syringes of various shapes and sizes without major modification.

The deployment of a shield in response to the axial displacement of a syringe barrel with respect to a holder is a safe and effective way of protecting against needle sticks. The preferred embodiment of the invention, as described above, provides advantages for the user as well as the manufacturer. The components are relatively easy to manufacture and assemble. It will be appreciated, however, that modifications can be made without changing the basic mode of operation of the device. For example, the stop member 58, rather than being in the form of a collar, can simply be the end of the shield. The stop member 48 and first detent 50 could be combined in a single element. It would also be possible to form the annular enclosure 46 at a different axial position. Connection of the spring to the end fitting and shield would obviate the need for the first detents. The spring would then function as a tether which would limit the axial movement of the shield. The dimensions of each component of the medical device are determined by the specific uses(s) for which it is designed.

It will be appreciated and understood by those skilled in the art that further and additional revisions to the invention may be devised without departing from the spirit and scope of the appended claims, the invention not being limited to the specific embodiments shown.

WHAT IS CLAIMED IS:

1. A medical device, comprising:

a syringe including a substantially cylindrical barrel and a needle connected to an end of said barrel;

a holder defining an enclosure, said barrel extending at least partially within said enclosure and being axially movable with respect to said holder;

a shield positioned within and connected to said holder, said shield having proximal and distal end portions and being axially movable with respect to said holder between retracted and extended positions;

an end fitting slidably coupled to said holder and engageable by said syringe;

a spring urging said shield towards its extended position, said spring having a distal end engaging said distal end portion of said shield and a second end engaging said end fitting;

a stop member positioned on said holder and engageable with said shield when said shield is in its retracted position, the force of said spring being insufficient to cause disengagement of said shield and stop member;

said syringe being operationally coupled to said shield such that sufficient axial movement of said syringe in the direction of said needle causes axial movement of said shield sufficient to cause disengagement of said shield and stop member, allowing said spring to move said shield to the extended position such that said shield covers said needle.

2. A device as described in Claim 1 wherein said end fitting is positioned within said shield.

3. A device as described in Claim 2 wherein said shield includes an enclosure, said second end of said spring being positioned within said enclosure.

4. A device as described in Claim 3 wherein said enclosure defines an end of said shield.

5. A device as described in Claim 4 wherein said end fitting includes a shoulder engaging said second end of said spring.

6. A device as described in Claim 1 including a retainer at a proximal end portion of said holder, said holder including a distal end portion including said stop member.

7. A device as described in Claim 6 including a flange extending from said proximal end portion of said holder.

8. A device as described in Claim 1 wherein said holder comprises an elongate, generally cylindrical body including a first detent and a second detent, said second detent being axially spaced from said first detent, said shield including a projection positionable between said first and second detents when said shield is in the extended position.

9. A device as described in Claim 1 wherein said end fitting includes a distal end adjoining said distal end portion of said shield.

10. A device as described in Claim 1 wherein said barrel includes radially outwardly extending flanges, and said holder comprises an elongate, generally cylindrical body having proximal and distal end portions, said proximal end portion of said holder including a retainer for slidably retaining said barrel flanges, said holder further including radially outwardly extending flanges at its proximal end portion.

11. A medical device, comprising:

a holder comprising an elongate body, an enclosure defined by said body, and proximal and distal open ends;

a syringe including a barrel and a needle secured to said barrel, said syringe being coupled to said holder and slidably positioned within said enclosure, said syringe being axially slidable within said enclosure;

an elongate shield positioned within and connected to said holder, said shield being operationally coupled to said syringe and axially movable upon axial movement of said syringe, said shield including proximal and distal end portions, said distal end portion of said shield including an engagement surface;

a spring coupled to said holder and urging said shield towards an extended position, said spring including an end portion abutting said engagement surface; and

a stop member mounted to said holder and releasably maintaining said shield in a retracted position wherein said needle is exposed when said syringe is in a first axial position, wherein said spring urges said shield to the extended position such that said second end portion extends beyond said needle when said syringe is moved to a sufficient distance in the direction of said needle.

12. A device as described in Claim 11 wherein said holder and said shield are generally cylindrical, said shield including a spring retainer which retains said end portion of said spring.

13. A device as described in Claim 11 including an elongate end fitting mounted to said holder, said shield being slidably mounted upon said end fitting, said spring engaging said end fitting.

14. A shield system for a syringe comprising:

a holder comprising an elongate body, an elongate enclosure defined by said body, and proximal and distal open ends,

an elongate shield connected to said holder and positioned at least partially within said enclosure, said shield including a passage extending therethrough and axially opposing proximal and distal openings to said passage, said shield being slidable within said enclosure between a retracted position wherein said distal opening is relatively near said distal open end of said holder and an extended position wherein said distal opening of said shield is relatively far from said distal open end of said holder;

a stop member mounted to said holder and engageable with said shield, said stop member being positioned to maintain said shield in the retracted position and release said shield upon sufficient axial displacement of said shield; and

a spring coupled to said holder and engaging said shield near said distal opening thereof.

15. A system as described in Claim 14 including an elongate end fitting slidably coupled to said holder, said spring being coupled to said holder by said end fitting.

16. A system as described in Claim 15 wherein said shield is slidably mounted upon said end fitting.

17. A system as described in Claim 16 wherein said shield includes a spring retainer near the distal opening thereof, said spring having an end retained by said spring retainer.

18. A system as described in Claim 14 including an elongate end fitting slidably mounted to said holder, said shield being slidably mounted upon said end fitting, said spring having a first end engaging said end fitting and a second end engaging said shield.

19. A system as described in Claim 18 wherein said first end of said spring extends over a distal end of said end fitting.

20. A system as described in Claim 19 wherein said shield includes a spring retainer near the distal opening thereof, said second end of said spring being retained by said spring retainer.

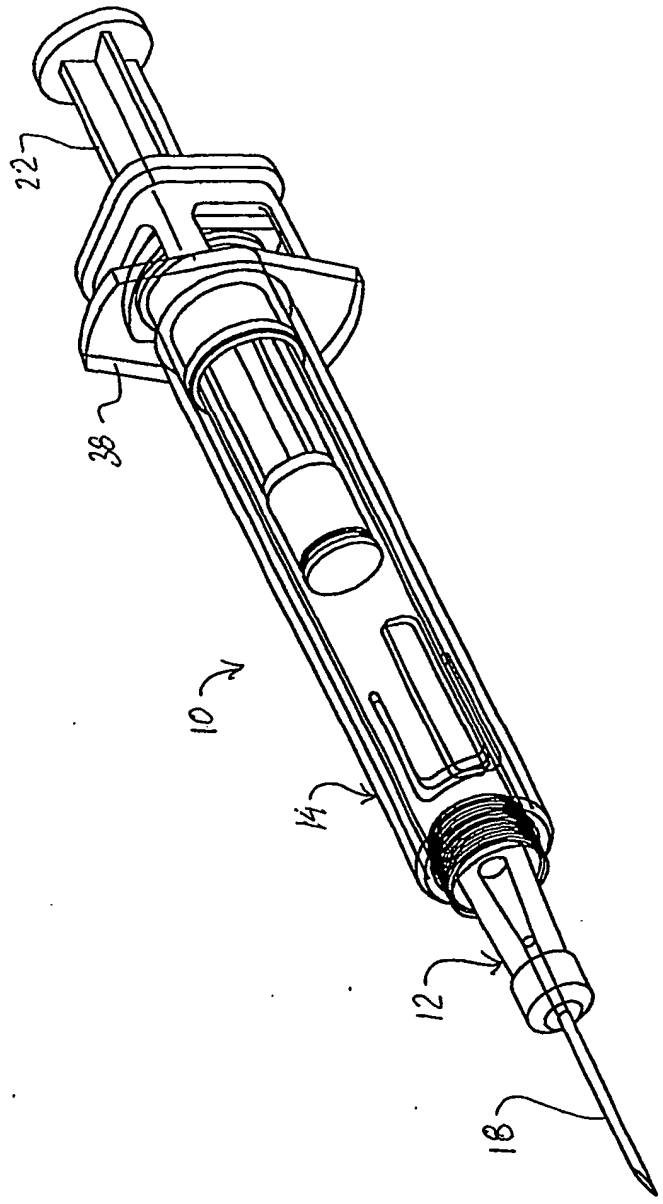


FIG-1

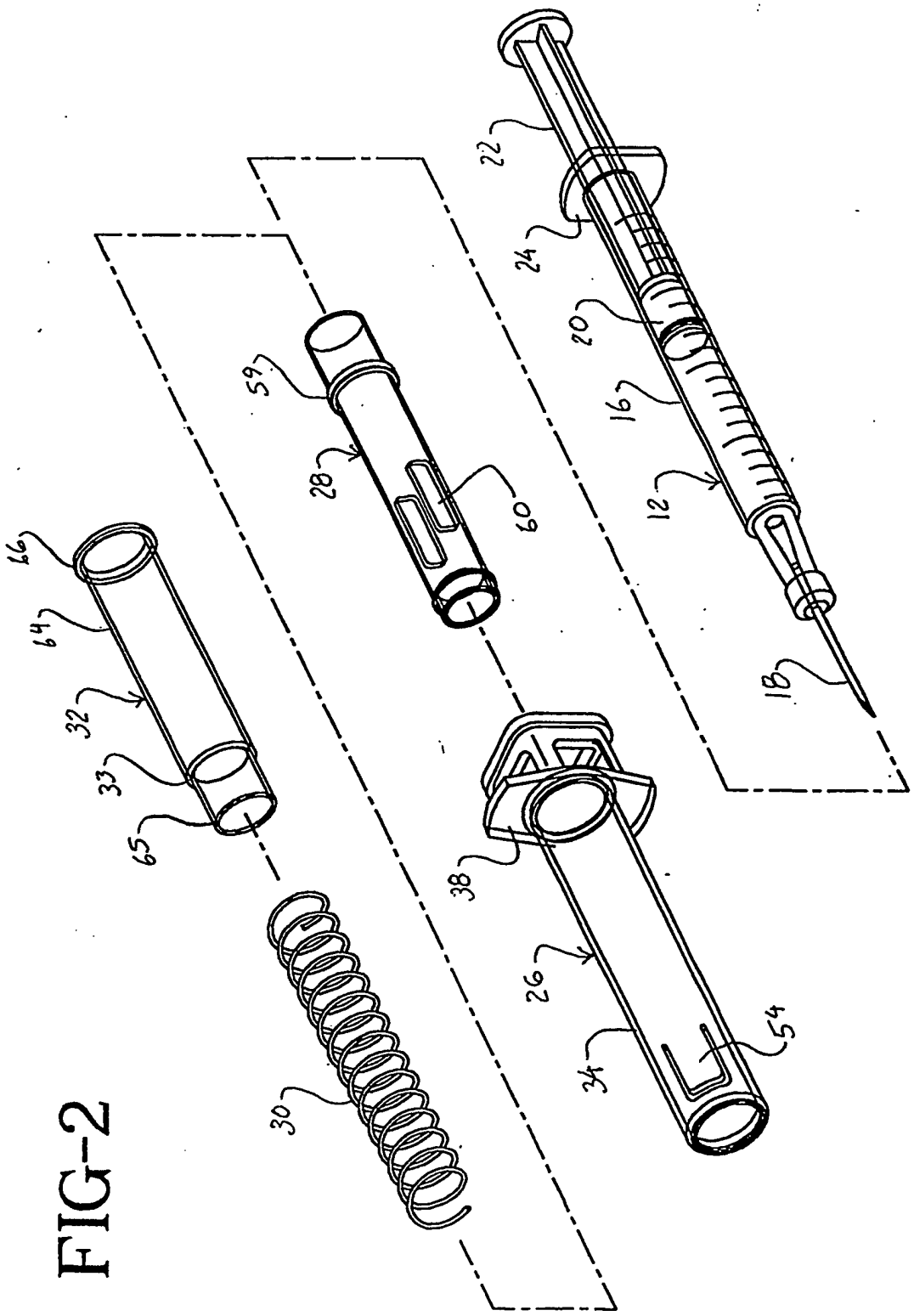
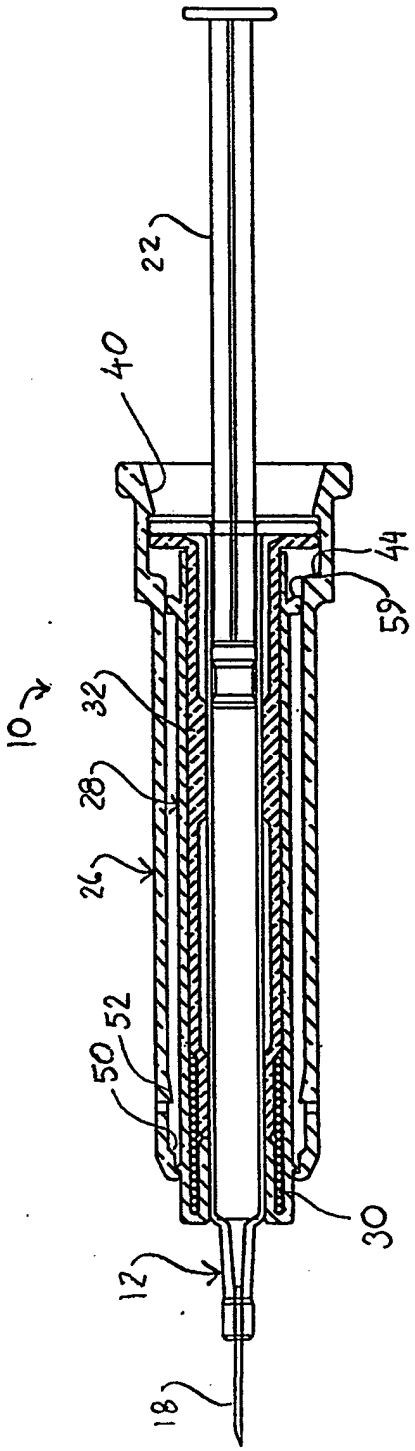


FIG-2

FIG-3



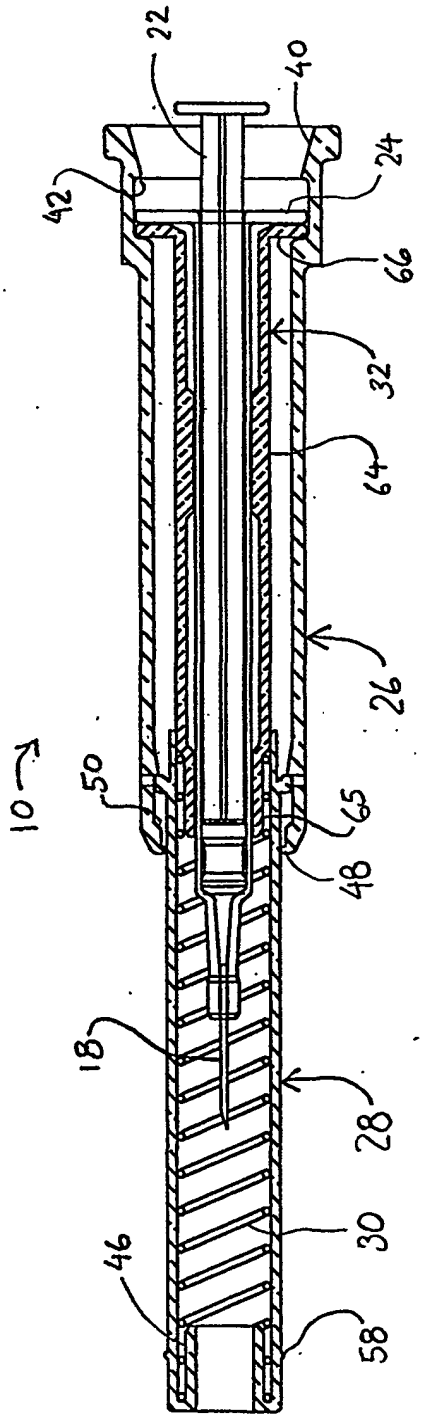
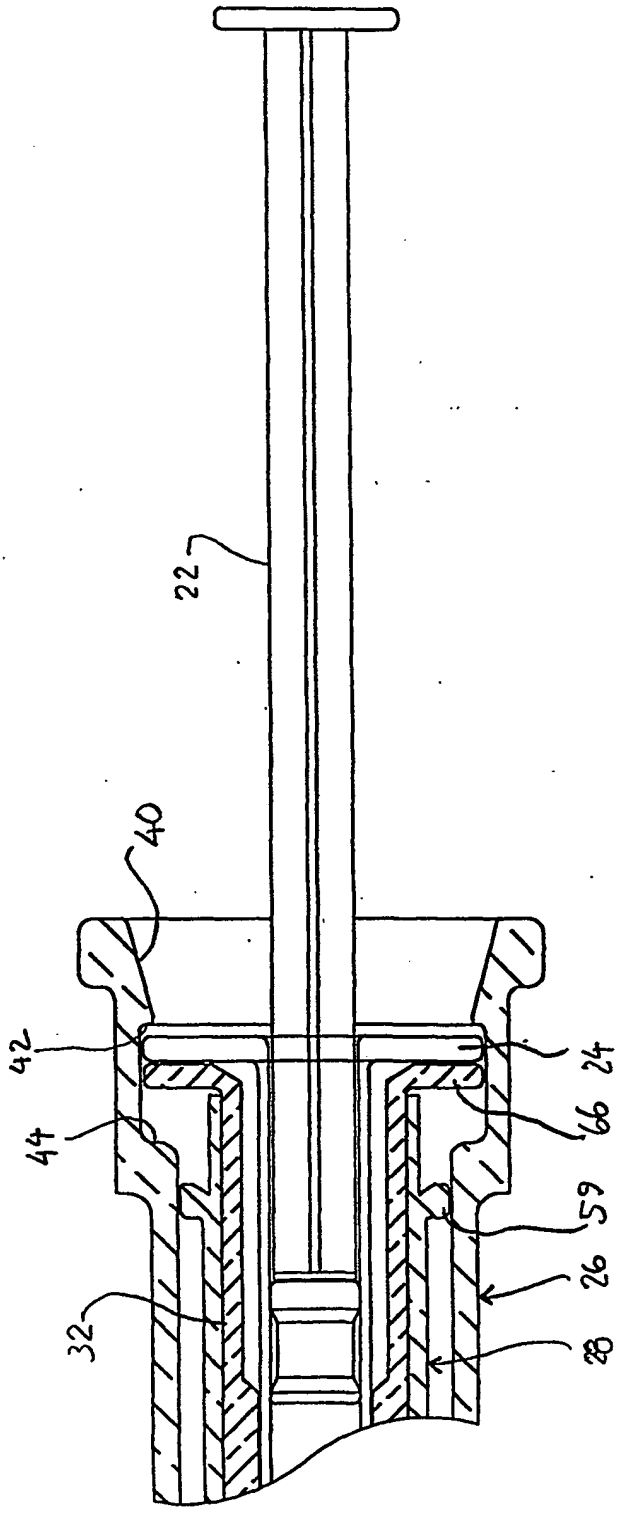


FIG-4

FIG-5



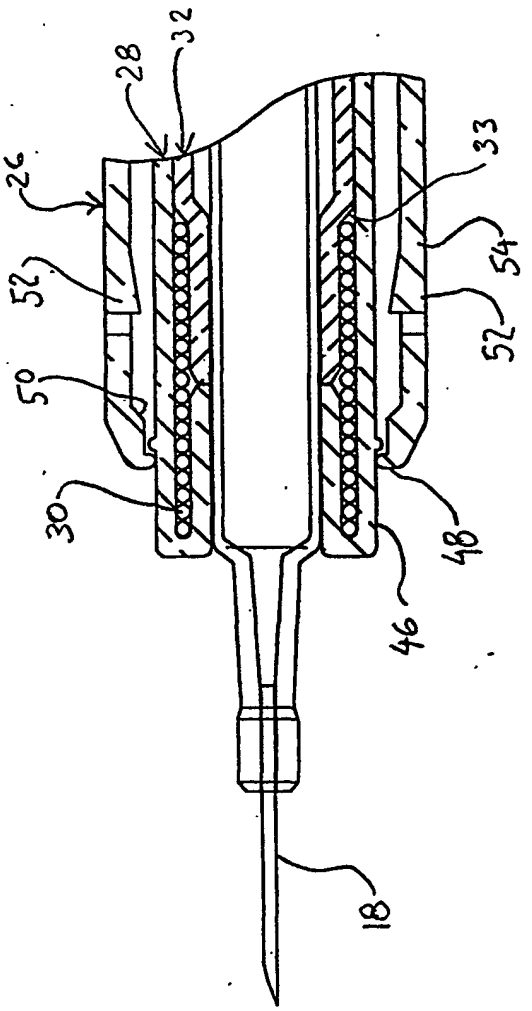


FIG-6

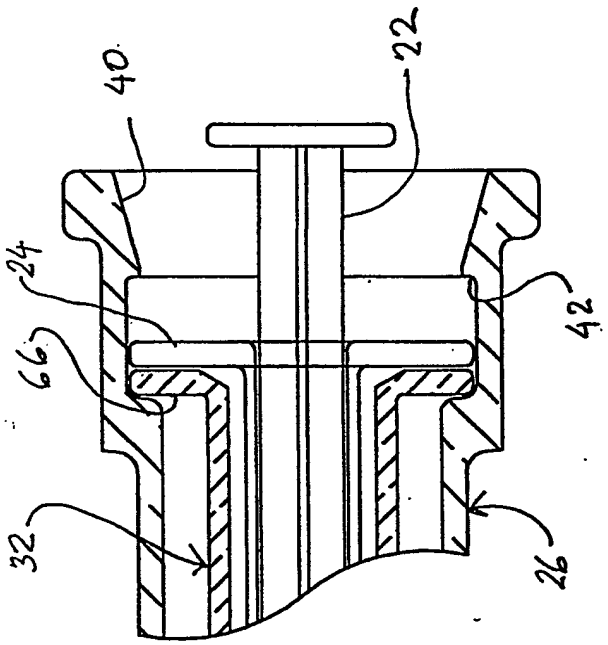


FIG-7

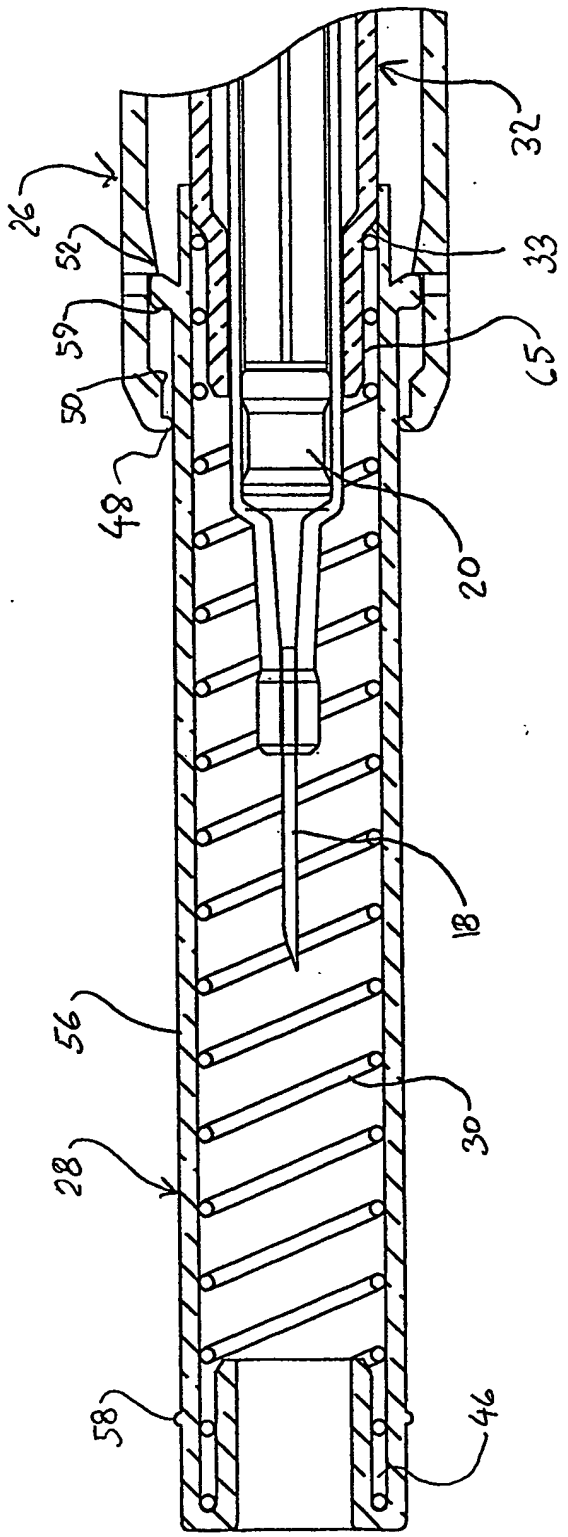


FIG-8

INTERNATIONAL SEARCH REPORT

ational Application No
PCT/US 02/19715

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 966 983 A (BECTON DICKINSON CO) 29 December 1999 (1999-12-29) column 2, line 54 - line 56; figures 1-19	1-20
A	US 5 591 138 A (VAILLANCOURT VINCENT L) 7 January 1997 (1997-01-07) column 6, line 15 - line 50; figure 6	1-20
P,X	WO 01 60435 A (SHAW DEREK JOSEPH ;ASTRAZENECA UK LTD (GB); LAW BRIAN ROBERT (GB);) 23 August 2001 (2001-08-23) the whole document	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the ISA	Authorized officer
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